

3587. Adulteration of Lobelia herb. U. S. v. 11 Bales * * *. (F. D. C. No. 30709. Sample No. 10773-L.)

LIBEL FILED: March 19, 1951, Southern District of Indiana.

ALLEGED SHIPMENT: On or about November 13, 1950, and January 5, 1951, by the Smoky Mountain Drug Co., from Bristol, Tenn.

PRODUCT: 11 bales, each containing from 81 to 183 pounds, of *Lobelia herb* at Tipton, Ind.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects, insect fragments, and rodent hair fragments.

DISPOSITION: June 5, 1951. The Smoky Mountain Drug Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for washing and pasteurizing, under the supervision of the Federal Security Agency. On June 20, 1951, the decree was amended to provide for release of the product for the purpose of extracting the alkaloids therefrom, in lieu of its release for washing and pasteurizing.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

3588. Adulteration and misbranding of conjugated estrogens. U. S. v. 1 Drum * * * (and 1 other seizure action). (F. D. C. No. 31317. Sample Nos. 10341-L, 10342-L.)

LIBELS FILED: July 3, 1951, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about January 5 and 11, 1951, by Strong Cobb & Co., Inc., from Cleveland, Ohio.

PRODUCT: 1 drum containing 52,400 tablets and 1 drum containing 33,200 tablets of *conjugated estrogens* at Detroit, Mich.

Analysis showed that 1 drum of the product (0.625 mg. tablets) contained a total amount of estrogenic steroids calculated as 0.40 mg. of sodium estrone sulfate per tablet and that the other drum of the product (1.25 mg. tablets) contained a total amount of estrogenic steroids calculated as 0.68 mg. of sodium estrone sulfate per tablet.

LABEL, IN PART: (Drum) "Contents 52400 * * * Name: Conjugated Estrogenic Hormone Substance * * * (0.625 mg. activity)" and "Contents 33200 * * * Name: Conjugated Estrogenic Hormone Substance Tablets (1.25 mg. activity)."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the articles differed from that which they were represented to possess, namely, 0.625 mg. per tablet and 1.25 mg. per tablet, respectively, of estrogens in their naturally occurring water-soluble conjugated form expressed as sodium estrone sulfate.

Misbranding, Section 502 (a), the following statements on the labels of the articles were false and misleading as applied to products which contained less than the stated amounts of total estrogenic steroids calculated as sodium estrone sulfate: "Formula contains at time of manufacture per tablet Estrogens (naturally occurring water-soluble conjugated form) expressed as sodium estrone sulfate 0.625 mg. * * *" and "Formula contains at time of manufacture per tablet Estrogens (naturally occurring water-soluble conjugated form) expressed as sodium estrone sulfate 1.25 mg. * * *."

*See also No. 3584.